

## Version with Markings to Show Changes Made

### In the Specification

Page 25, fourth paragraph (AMENDED)

The compound (V) has a superior effect as a pharmaceutical and shows a superior inhibitory activity particularly against steroid C<sub>17,20</sub> lyase. The compound (V) shows low toxicity and fewer side effects. Therefore, it is useful as an agent for the treatment and prevention of various diseases in mammals (e.g., humans, bovines, horses, dogs, cats, monkeys, mice, rats etc., particularly humans) such as (1) primary carcinoma of malignant tumor (e.g., prostate cancer, breast cancer, uterine cancer, ovarian cancer etc.), and metastatic cancer and recurrent carcinoma thereof, (2) various symptoms associated with these cancers (e.g., pain, cachexia etc.), (3) prostatic hypertrophy, **[musculinism] masculinism**, hypertrichiasis, male-pattern baldness, male infantile precocity, endometriosis, hystero myoma, adenomyosis of uterus, mastopathy, polycystic ovary syndrome and the like.

Page 25, sixth paragraph (AMENDED)

As the therapy to be combined, there are mentioned, for example, operation, thermotherapy, radiation therapy and the like. Together with chemotherapy including administration of the compound (V), for example, a therapeutic method other than chemotherapy, such as an operation inclusive of **[orchidectomy] orchiectomy**, thermotherapy, radiation therapy and the like, can be used in combination.

**In the Claims**

Claim 35 (Once Amended) The production method described in claim (1)[, (2), (3) or (4),] wherein R is a lower alkenyl group, a cycloalkyl group, a phenyl group, a pyridyl group, or a lower alkyl group optionally substituted by a halogen atom.

## **REMARKS**

### **I. Amendments**

Claim 35 has been amended and claims 15 and 16 have been canceled.

This amendment adds no new matter to the specification. Support for this amendment is found in the specification and claims as filed. Typographical and grammatical errors have also been corrected throughout the specification.

Attached hereto is a marked-up version of the changes made to by the current amendment. The attached pages are captioned "Version with Markings to Show Changes Made".

No change of inventorship is necessitated by this amendment.

### **II. Discussion of the Status of the Pending Claims**

In the Office Action at page 3, the Examiner has indicated that claims 1, 5-9 and 11-14 are allowable. However, on the Office Action Summary Sheet, the claims 1, 5-9 and 11-14 are listed as objected to. No objection is provided in the Office Action. Applicants respectfully request clarification of the status of the claims. If they are objected to, Applicants request that the Examiner specifically state any objections she may have.

### **III. Discussion of the Previously Submitted Supplemental Information Disclosure Statement**

A Supplemental Information Disclosure Statement was filed on December 12, 2002. Applicants respectfully request consideration of the filed Supplemental Information Disclosure Statement.

#### **IV. Discussion of the Second Supplemental Information Disclosure Statement**

A Second Supplemental Information Disclosure Statement accompanies this response. Applicants respectfully request consideration of the pending claims in light of the Second Supplemental Information Disclosure Statement.

#### **V. Discussion of the Objection to Claim 35**

Claim 35 has been objected to under 37 C.F.R. Sec. 1.75(c) as being in improper form.

By this amendment, Applicants have amended claim 35 to be solely dependent from claim 1.

Therefore Applicants respectfully request withdrawal of the 37 C.F.R. Sec. 1.75 (c) objection to claim 35.

#### **VI. Discussion of the Rejection under 35 U.S.C. Sec. 103(a) over Iwasaki *et al.***

Claims 15-17 have been rejected under 35 U.S.C. Sec. 103(a) as allegedly obvious over Iwasaki *et al.* (Helv. Chim. Acta, 1976). Applicants respectfully traverse the rejection.

By this amendment, claims 15 and 16 have been cancelled.

The full text of the cited article accompanies this response as Appendix A. Applicants respectfully request the Examiner's consideration of claim 17 in light of the full reference.

Therefore Applicants respectfully request withdrawal of the rejection under 35 U.S.C. Sec. 103(a) over Iwasaki *et al.*

## VII. Conclusion

Reconsideration of the claims as amended and allowance is requested. Should the Examiner believe that a conference with Applicants' attorney would advance prosecution of this application, the Examiner is respectfully requested to call Applicants' attorney at (847) 383-3391.

Respectfully submitted,

Dated: February \_\_, 2003

(847) 383-3391

(847) 383-3372

Elaine M. Ramesh, Ph.D., Reg. No. 43,032

Mark Chao, Ph.D., Reg. No. 37,293

Attorney for Applicants

Customer No. 23,115

Takeda Pharmaceuticals North America, Inc.  
Intellectual Property Department  
Suite 500, 475 Half Day Road  
Lincolnshire, IL 60069 USA

### Certificate of Mailing under 37 CFR 1.10

The undersigned hereby certifies that this document, along with any attachments, is being deposited in an envelope addressed to The Commissioner of Patents and Trademarks, with sufficient postage with the United States Postal Service EXPRESS MAIL Post Office to Addressee Service on this date February 6, 2003.

Express Mail Label No. EV 193976147 US

Gail L. Winokur

Printed Name: Gail L. Winokur